REMARKS

This is in response to the Official Action of January 19, 2006 in connection with the above-identified application. Applicants have amended the claims of the instant application in order to more precisely define the scope of the present invention.

Specifically, Applicants have amended claims 1, 3, 14 and 19 to recite inhibition of influenza virus infection in place of reciting inhibition of viral infection. Support for this amendment may be found throughout the specification as originally filed, including, e.g., page 3, line 23 through page 4, line 7.

The rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. §112, second paragraph, as being indefinite has been carefully considered but is most respectfully traversed in light of the following comments.

The Official Action urges that the structure of spirulina growth factor is unclear from the specification of the instant application. The Official Action urges that the specification does not provide a definition for spirulina growth factor. Applicants respectfully traverse this position.

Firstly, Applicants direct attention to page 3, lines 10 through 20 of the instant application for a definition of spirulina growth factor. The specification indicates that SGF is a mixture which contains nucleic acid, nucleotides, small molecule proteins, sulfur-containing polysaccharides and water soluble vitamins and minerals. The specification continues that SGF is rich in polysaccharides, which are known to boost the immune system and posses anti-viral and anti-tumor activities, including sulfur-containing polysaccharides, which have been found to be effective against AIDS and other viruses.

Furthermore, Applicants respectfully submit that one of ordinary skill at the time of filing the instant application would understand the definition of SGF. For example, the Far East Microalgae Co., Ltd of Taipei, Taiwan distributes SGF in powder and liquid form and describes SGF as hot water extract of Spirulina. It is a mixture of all the water-soluble ingredients in Spirulina and is composed of nucleic acids, peptides, water soluble vitamins and minerals.

Applicants also note that the method extracting SGF is modified from the well known method of extracting Chlorella growth factor (CGF) involving the concentration of nucleotides, ceratin peptides or proteins and other ingredients. The SGF extraction process comprises (a) adding 100 g blue algae powder into 900 ml water and mixing evenly; (b) steam sterilizing the mixture at 120°C for 60 minutes; (c) cooling the mixture and centrifuging the mixture at 8000 rpm for 30 minutes and (d) collecting the supernatant, which comprises SGF.

Finally, Applicants enclose herewith an absorption spectrum of SGF powder, which further defines the structure of SGF and illustrates that the structure of SGF is well known in the art.

In light of the above, Applicants respectfully submit that the structure of SGF is both defined in the instant application and is also well know to those of ordinary skill in the art, and therefore respectfully request that the §112, second paragraph, rejection of claims 1-4, 9, 11-17 and 19 be withdrawn.

The rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement has been carefully considered but is most respectfully traversed in light of the following comments.

The Official Action urges that spirulina growth factor must be known and readily available to the public or obtainable by a repeatable method in order for the specification of the instant application to enable the claims of the instant application. As discussed in detail above, SGF is both known and available to the public, as well as obtainable by a repeatable method. Applicants respectfully submit that the definition of SGF is established in the instant application and that one of ordinary skill in the art would know what SGF is. Furthermore, a method of obtaining SGF based on a method of extracting CGF known in the art is provided, thereby making SGF readily available. Accordingly, Applicants respectfully submit that the specification fully enables the claims with respect to the recitation of SGF and request that the §112, first paragraph rejection, of claims 1-4, 9, 11-17 and 19 be withdrawn.

The rejection of claims 1-4, 9, 11-17 and 19 under 35 U.S.C. §112, first

paragraph, as failing to comply with the enablement requirement has been carefully considered but is most respectfully traversed in light of the following comments.

The Official Action urges that the claims of the instant application are drawn to agents that inhibit any viral infection in any host comprising compositions containing various amounts of C-phycocyanin, allophycocyanin and SGF, yet the specification of the instant application does not demonstrate that the claimed composition can inhibit any viral infection in any host. The Official Action urges that without information such as *in vivo* or *in vitro* experimentation, one of ordinary skill in the art would not now how to make or use the claimed invention. Applicants respectfully traverse this position.

To begin with, Applicants note that the claims of the instant application have been amended to recite inhibition of influenza virus infection. Accordingly, the assertion that the claims are drawn to agents that inhibit any viral infection is no longer accurate. Rather, the preamble of claims now recites a composition for inhibition of influenza virus infection.

Secondly, Applicants note that the claims of the instant application are drawn to a composition, and not a method of inhibiting any viral infection or influenza virus infection. While the preamble of the claims recites that the oral composition is for inhibiting influenza virus infection, the body of the claims recites a composition comprising C-phycocyanin, allophycocyanin and SGF. Accordingly, Applicants respectfully submit that the issue of enablement does not go to whether one of ordinary skill in the art would know how to make and/or use a method of inhibiting any viral infection or influenza virus infection as the Official Action appears to suggest, but rather goes to whether the specification enables one of ordinary skill in the art to make and/or use the composition claimed in the instant application. Applicants respectfully submit that this is achieved by the specification, and therefore Applicants respectfully submit that the enablement requirement is satisfied.

"[A] specification disclosure which contains a teaching of the manner of process of making and using the invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as in

compliance with the enabling requirement of the first paragraph of § 112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." In re Marzocchi, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971)(emphasis in original). "[It] is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement." Id. at 224, 169 USPQ at 370.

As noted above, the Official Action appears to focus on whether the specification enables claims directed to a method for inhibiting viral infection. However, the claims are composition claims, and the Official Action has provided no evidence which explains why it doubts that the composition can be made or used in the manner described in the specification.

With respect to making the composition, the specification sets forth both an example for preparing the oral composition of the present application and also an example for adding the oral composition to a drink (see, e.g., pages 8-10). Accordingly, the method of making the composition is clearly set forth in the specification and the Official Action has provided no reason why it doubts the objective truth of the statements contained in the specification with respect to making the composition. Therefore, Applicants respectfully submit that the specification complies with the enablement requirement.

Similarly, the specification clearly sets forth how to use the composition. As stated in the claims, the compositions are oral compositions, and are therefore taken by mouth. As explained in the specification, the composition can be taken in capsule form or may be added to drink or food (see, e.g, page 7, lines 3-8). The Official Action has provided no reason why it doubts the objective truth of the statements contained in the specification with respect to using the composition. Accordingly, Applicants respectfully submit that the specification complies with the enablement requirement and therefore request that the §112, first paragraph rejection be withdrawn.

Even assuming, *arguendo*, that the specification must enable a method of inhibiting influenza virus infection, Applicants respectfully submit that the specification of the instant application accomplishes this. Applicants respectfully submit that, based on the specification of the instant application, one of ordinary skill in the art at the time of the invention would be able to use the composition for inhibiting influenza virus infection without undue experimentation.

Firstly, as noted above, the claims of the instant application have been amended to recite a composition for inhibiting influenza virus infection in place of inhibiting viral infection. Therefore, contrary to the position taken in the Official Action, the specification need not enable one of ordinary skill to use the composition to inhibit all viral infection in any host without undue experimentation. Rather, the focus must be shifted to whether the specification enables the use of the composition to inhibit influenza virus infection.

Applicants respectfully submit that one of ordinary skill in the art, through only routine experimentation, would know how to use the claimed composition for inhibiting influenza virus based on the specification of the instant application. As clearly stated in the specification, phycocyanin has already been proven to inhibit the infection of influenza viruses at concentrations greater than 0.04 μM. Applicants respectfully submit that this serves as enabling disclosure that would allow one of ordinary skill in the art to know how to use the claimed invention, which contains two types of phycocyanin as at least 4% and as much as 60% of the claimed composition, to inhibit influenza virus.

As discussed above, it has been held that the specification must be deemed in compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, unless the Patent Office provides acceptable evidence to support its doubt of the objective truth of the statements contained in the specification. Applicants respectfully submit that the Official Action has not provided acceptable evidence to support such doubt, and thus the burden of establishing a §112, first paragraph, enablement rejection has not been carried.

Rather, the Official Action presents broad, unsupported statements such as

"[O]ne of ordinary skill in the art would not expext C-phycocyanin and/or allophycocyanin and/or Spirulina growth factor to inhibit virus entry of any virus without having seen proof that it works in at least an acceptable animal model of viral infection". No references have been provided in support of such an allegation. The Official Action also appears to engage in an abbreviated Wands analysis at page 4 and 5 of the Official Action, yet none of the allegations set forth are supported by any type of evidence. As the Official Action has failed to carry the burden of establishing a foundation for doubting the enablement of the specification, Applicants respectfully submit that a proper §112, first paragraph, rejection for lack of enablement has not been established and should therefore be withdrawn.

Finally, as noted briefly above, Applicants respectfully submit that one of ordinary skill in the art at the time of the invention would have known how to use the composition based on the specification without the need for undue experimentation. Rather, any experimentation required would be routine and not undue. Applicants provide herewith an example of experimentation conducted on mice that is based on what would have been known by one of ordinary skill in the art at the time of the invention in light of the specification. Applicants respectfully submit that such experimentation would not qualify as undue and would allow the skilled artisan to use to the claimed invention to inhibit influenza virus infection.

Applicants provide *in vivo* data showing that the oral composition in the present invention inhibits influenza virus infection. The experimental data is as follows.

Group I	Gavaged with 1500pfu type A influenza virus and the prepared oral agent.
Group II	Gavaged with 150 pfu type A influenza virus and the prepared oral agent.
Group III	Gavaged with 15 pfu type A influenza virus and the prepared oral agent.

Control group A	Gavaged with the prepared pharmaceutical composition without virus.
Control group B	Gavaged with 1500pfu type A influenza virus and phosphate buffer solution (PBS).
Control group C	Gavaged with 150pfu type A influenza virus and phosphate buffer solution.
Control group D	Gavaged with 15pfu type A influenza virus and phosphate buffer solution.

Mice in the experimental groups were anesthetized by Ketamine (1mg per mouse) and immediately gavaged with type A influenza virus (Influenza WSN virus at 1500pfu, 150pfu, and 15pfu). The control groups went through the same procedure, but received no virus and PBS only.

To observe the ability of the composition to inhibit influenza virus infection, mice in the experimental groups were given the claimed composition once a day for six days consecutively after they first received the virus for 6 hours later. The dose given was 18mg/kg. The mice were reared for eight days. Daily observation of weight change and mortality was carried out.

The results as shown in Table 1 and Table 2 demonstrate that mice in Control group B, C and D that were given only virus but no oral composition died on day 4 (1500pfu), day 5 (150pfu) and day 7 (15pfu) after viral infection. But mice in the experimental groups that were given both virus and oral composition survived. Although those mice showed mild symptom of illness accompanied with weight loss in the beginning, they all recovered gradually and gained weight again. The body weight of mice in the control group that were given only the oral composition without virus increased with time.

As shown in the following results of the experiment, the oral composition according to the present invention can totally prevent the death of mice infected with type A influenza virus and can be used to inhibit the activity of such virus.

Table 1 Weight Change and Mortality Record of Mice in Control Groups

	Control group A	Control group B	Control group C	Control group D
Virus	-	1500pfu	150pfu	15pfu
Oral Composition	+	-	-	-
Weight (g) Day 0	19.10	19.21	19.23	19.08
Day 1	19.53↑	18.01	18.57	19.01
Day 2	20.57↑	16.51	17.11	18.35
Day 3	21.50↑	Dead	16.11	17.31
Day 4	22.67↑		Dead	17.34
Day 5	23.50↑			16.31
Day 6	24.63↑			Dead
Day 7	25.73↑			
Day 8	Survived			

Table 2 Weight Change and Mortality Record of Mice in Experimental Groups

	Control group I	Control group II	Control group III
Virus	1500pfu	150pfu	15pfu
Oral Composition	+	+	+
Weight (g) Day 0	19.16	19.25	19.66
Day 1	18.54	18.51	19.11
Day 2	18.91	18.98	19.49
Day 3	18.91	19.26↑	18.85
Day 4	19.34↑	19.63↑	19.13↑
Day 5	19.76↑	19.93↑	19.16↑
Day 6	19.79↑	20.14↑	19.66↑
Day 7	19.81↑	20.36↑	20.01↑
Day 8	Survived	Survived	Survived

As shown in the results, experimental animals that were given the oral composition beforehand were able to recover from the influenza virus-induced symptoms, while control group animals which were not administered with the composition died, indicating its efficacy in inhibiting the reproduction of type A influenza virus and hence preventing influenza virus infection.

In summary, Applicants respectfully submit that the invention claimed in the instant application, i.e., an oral composition comprising C-phycocyanin, allophycocyanin and SGF, is enabled by the specification and therefore the claims comply the enablement requirement of 35 U.S.C. §112. Based upon the specification, one of ordinary skill in the art at the time of invention would know how to make and/or use the composition without undue experimentation. Furthermore, because the claims are now drawn to a composition for inhibiting influenza virus infection and not treatment of all virus, Applicants respectfully submit that the comments set forth in the Official Action with respect to the §112, first paragraph enablement rejection are moot. Finally, Applicants respectfully submit that, based upon the specification, one of ordinary skill in the art at the time of the invention would know how to use the composition for inhibiting influenza virus infection without undue experimentation. For each of these reasons, Applicants respectfully request that the §112, first paragraph rejection of claims 1-4, 9, 11-17 and 19 be withdrawn.

Finally, Applicants note the comments set forth in the Official Action regarding Applicant's representative's summary of the telephone interview conducted April 12, 2006. The Official Action urges that Applicant's representative took great liberties in summarizing the content of the interview with respect to statements made by the Examiner regarding the cited prior art references. Applicant's representative apologizes for any perceived mischaracterization of the contents of the interview. However, after carefully reviewing the summary of the interview set forth in the Response filed April 19, 2006, Applicant's representative respectfully maintains the position that the summary represents an accurate account of what transpired during the telephone interview. Applicant's representative respectfully invites the Examiner, should she so choose, to

more specifically identify those portions of the summary which are perceived as inaccurate as well as provide the Examiner's account of the telephone interview.

In view of the above comments and further amendments to the claims, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,
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